

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 3 is rejected under 35 U.S.C. 102(e) as being anticipated by Falconer (US 2003/0073974). Falconer discloses an irrigation system comprising a reservoir (1) for irrigating a liquid (abstract), a probe (7) for arrangement in a user, a conduit (6) for conducting the irrigating fluid from the reservoir to the probe, a fixation member including an inflatable cuff (Figs. 1 and 4, 14) for fixation of the probe in the user, a pump (5) for pumping for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe, a control unit which may be set in at least an inactive position, a cuff inflating position in which gas is pumped into the inflatable cuff and a liquid transferring position (the term "control unit" is very broad and can be interpreted as anything that controls. Therefore, the examiner is interpreting the clamp 15 in Fig. 1 as the control unit, as when it is activated or in the clamped position, it prevents fluid flow and prevents the cuff from inflating and when it is not activated or not clamping, it allows both liquid transferring and cuff inflation. Therefore the control unit 15 may be set in an inactive position (clamped position) as well as a cuff inflating position and a

liquid transferring position, as these two positions are the same when 15 is open), said conduit including a first part connecting the control unit with the probe (the first part is the portion of the conduit between 15 and 14) and a second part connecting the reservoir with the control unit (the second part is the portion between 6a and 15), each of said first and second parts including a gas conducting tube and an irrigating liquid conducting tube (the tubing on either side of 15 is shown to conduct liquid and is also perfectly capable of conducting gas and the claim language does not require that the gas and liquid conducting tubes be separate from each other).

Claim 6 is rejected under 35 U.S.C. 102(e) as being anticipated by Falconer (US 2003/0073974). Falconer discloses an irrigation system comprising a reservoir (1) for irrigating a liquid (abstract), a probe (7) for arrangement in a user, a conduit (6) for conducting the irrigating fluid from the reservoir to the probe, a fixation member including an inflatable cuff (Figs. 1 and 4, 14) for fixation of the probe in the user, a pump (5) for pumping for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe, a control unit which may be set in at least an inactive position, a cuff inflating position in which gas is pumped into the inflatable cuff and a liquid transferring position (the term "control unit" is very broad and can be interpreted as anything that controls. Therefore, the examiner is interpreting the clamp 15 in Fig. 1 as the control unit, as when it is activated or in the clamped position, it prevents fluid flow and prevents the cuff from inflating and when it is not activated or not clamping, it allows both liquid transferring and cuff inflation. Therefore the control unit 15 may be

set in an inactive position (clamped position) as well as a cuff inflating position and a liquid transferring position, as these two positions are the same when 15 is open), in which gas is pumped into the reservoir and irrigating liquid is transferred from the reservoir to the probe.

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Falconer (US 2003/0073974). Falconer discloses an irrigation system comprising a reservoir (1) for irrigating liquid (abstract), a probe (7) for arrangement in a user, a conduit (6) for conducting the irrigating fluid from the reservoir to the probe, a fixation member including an inflatable cuff (Figs. 1 and 4, 14) for fixation of the probe in the user, a pump (5) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe, and a control unit which may be set in at least a cuff inflating position and a liquid transferring position (the term "control unit" is very broad and can be interpreted as anything that controls. Therefore, the examiner is interpreting the clamp 15 in Fig. 1 as the control unit, as when it is activated or in the clamped position, it prevents fluid flow and prevents the cuff from inflating and when it is not activated or not clamping, it allows both liquid transferring and cuff inflation. Therefore the control unit 15 may be set in an inactive position (clamped position) as well as a cuff inflating position and a liquid transferring position, as these two positions are the same when 15 is open), said control unit including at least two elements that may be moved with respect to each other into at least said cuff inflating and liquid transferring positions, the

elements comprising a cylindrical element and an accommodating element having a substantially cylindrical aperture with dimensions corresponding substantially to the dimensions of the cylindrical element, said cylindrical element being rotatable about an axis of rotation with respect to the accommodating element, and said cylindrical element being settable in at least said cuff inflating and liquid transferring positions (the control unit according to paragraph [0018] can be either clamp or a tap, and a tap would have two elements that move with respect to each other such as for example a stop cock-type tap which would also have the cylindrical element and accommodating element as well as the apertures), at least irrigating liquid conducting tubes (6) connecting the control unit with the probe and the reservoir.

Claims 23 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Falconer (US 2003/0073974). Falconer discloses an irrigation system comprising a reservoir (1) for irrigating liquid (abstract), a probe (7) for arrangement in a user, a conduit (6) for conducting the irrigating fluid from the reservoir to the probe, a fixation member including an inflatable cuff (Figs. 1 and 4, 14) for fixation of the probe in the user, a pump (5) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe and a control unit which may be set in at least a cuff inflating position and a liquid transferring position (the term "control unit" is very broad and can

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be interpreted as anything that controls. Therefore, the examiner is interpreting the clamp 15 in Fig. 1 as the control unit, as when it is activated or in the clamped position, it prevents fluid flow and prevents the cuff from inflating and when it is not activated or not clamping, it allows both liquid transferring and cuff inflation. Therefore the control unit 15 may be set in an inactive position (clamped position) as well as a cuff inflating position and a liquid transferring position, as these two positions are the same when 15 is open), said pump being a powered pump (the term "powered pump" is broad enough to include a pump that is powered by anything, such as being powered by the squeezing action of a human hand, etc.) and being deactivated when the control unit is set in a first position and being activated automatically when the control unit is set in a second position (when the clamp/tap (15) is in the open position, the air that has been pumped into the container 2 will automatically activate a pumping of the liquid from the reservoir 1 out through the conduit 6 and into the probe. However, when the clamp/tap (15) is in the closed position, the pump is deactivated as the air that has been pumped into the container 2 will not be able to force the liquid past the control unit/clamp/tap 15 and into the probe for use).

In reference to claim 26, Falconer discloses that the pump is pneumatically operated (air is pumped into container 2 and this forces the water out of the reservoir).

Claims 24 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Falconer (US 2003/0073974). Falconer discloses an irrigation system comprising a

reservoir (1) for irrigating liquid (abstract), a probe (7) for arrangement in a user, a conduit (6) for conducting the irrigating fluid from the reservoir to the probe, a fixation member including an inflatable cuff (Figs. 1 and 4, 14) for fixation of the probe in a user, a pump (5) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe and a control unit which may be set in at least a cuff inflating position and a liquid transferring position (the term "control unit" is very broad and can be interpreted as anything that controls. Therefore, the examiner is interpreting the clamp 15 in Fig. 1 as the control unit, as when it is activated or in the clamped position, it prevents fluid flow and prevents the cuff from inflating and when it is not activated or not clamping, it allows both liquid transferring and cuff inflation. Therefore the control unit 15 may be set in an inactive position (clamped position) as well as a cuff inflating position and a liquid transferring position, as these two positions are the same when 15 is open), said pump being a manually operated pump (5 is operated by a hand squeezing it), which is integrated with the control unit (5 is integrated with the control unit as they are all connected together via various connections).

In reference to claim 27, Falconer discloses that the pump is a bulb pump (5).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falconer (US 2003/0073974) in view of Evanoski, III (US Patent No. 4,367,740). Falconer discloses an irrigation system comprising a reservoir (1) for irrigating liquid (abstract) a probe (7) for arrangement in a user, a conduit (6) for conducting the irrigating fluid from the reservoir to the probe, a fixation member including an inflatable cuff (Figs. 1 and 4, 14) for fixation of the probe in the user, a pump (5) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe, and a control unit which may be set in at least a cuff inflating position and a liquid transferring position (the term "control unit" is very broad and can be interpreted as anything that controls. Therefore, the examiner is interpreting the clamp 15 in Fig. 1 as the control unit, as when it is activated or in the clamped position, it prevents fluid flow and prevents the cuff from inflating and when it is not activated or not clamping, it allows both liquid transferring and cuff inflation. Therefore the control unit 15 may be set in an inactive position (clamped position) as well as a cuff inflating position and a liquid transferring position, as these two positions are the same when 15 is open). Falconer,

however, does not disclose that there are three flexible tubes connected to the control unit. Evanoski, however, discloses an irrigating system (Figs. 1 and 2) which comprises a probe (14) with an inflatable cuff (16) as well as a pump/control unit (29). Evanoski further discloses that there are three flexible tubes connected to the pump (19, 21, 15 and 28 are all connected to the pump) and that the first tube is connected to a gas outlet (tube 19 is connected to a gas outlet 32), the second tube is connected to the reservoir (28 is connected to the reservoir 26 as seen in Fig. 7) and the third tube is connected to the inflatable cuff (15 is connected to the cuff as seen in Fig. 3). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Falconer with the tubing arrangement as taught by Evanoski, in order to provide an irrigation system that allows for multiple connections and multiple arrangements of the device allowing for more versatility.

In reference to claim 28, Falconer discloses that the tubes are individually compressed to prevent fluid flow therethrough (the clamp 15 would compress the tubes to prevent fluid flow).

#### ***Allowable Subject Matter***

Claims 7-12 are allowed. The following is an examiner's statement of reasons for allowance: The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was a control unit comprised of a first disc, second disc and intermediate disc, the intermediate disc being rotatable with respect to the first and second discs, the rotation setting the cuff



inflating and liquid transferring positions, in combination with the other elements of the claims.

Claims 14-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Upon reviewing the claims and prior art, it is the examiner's position that the claims are still broad enough, particularly the "control unit" phrase, and that the Falconer reference is still applicable.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767